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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/402,405 10/04/99 GILVARG

C PRIN-0064

EXAMINER

HM12/0524

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ART UNIT	PAPER NUMBER

1623
DATE MAILED:

4
05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/402,405

Applicant(s)
Charles Gilvarg

Examiner
Louise Leary

Group Art Unit
1623



☒ Responsive to communication(s) filed on Dec 13, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 4 and 5 is/are allowed.

☒ Claim(s) 1-3 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. Claims 1-5 are pending in this application.
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al (US PATENT Number 4,551,272).

Sugiyama et al disclose an assay for measuring enzymatic activity of carboxypeptidase A in the sample in the presence or absence of a reaction inhibitor. Sugiyama et al disclose that carboxypeptidase A enzyme is found in the pancreas and the blood serum. Sugiyama et al also disclose a method wherein the activity of the carboxypeptidase A enzyme was measured. In addition, Sugiyama et al disclose that the activity of the enzyme carboxypeptidase A depends on the disease which is present and the extent of the disease. See the abstract and columns 1-10.

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Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al (US PATENT Number 4,432,896).

Sugiyama et al disclose an assay for measuring enzymatic activity of carboxypeptidase A in a sample in the presence or absence of a reaction inhibitor. Sugiyama et al disclose that carboxypeptidase A enzyme is a protein-decomposing enzyme found in the pancreas and the blood serum. Sugiyama et al also disclose a method wherein the activity of the carboxypeptidase A enzyme was measured. In addition, Sugiyama et al disclose that the activity of the enzyme carboxypeptidase A depends on the disease which is present and the extent of the disease. See the abstract and columns 1-4.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (Analytical Biochem., Vol.161, p219-225, (1987) in combination with Talley (US Patent 4939288 (1990)).

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The claims are directed to a method of enhancing sensitivity and specificity of an assay measuring enzymatic activity in a sample comprising measuring enzymatic activity in the sample in the presence and absence of a specific inhibitor of the enzymatic activity; a method of measuring carboxypeptidase A levels in a biological fluid by contacting the fluid with a carboxypeptidase A substrate in the presence and absence of an inhibitor of carboxypeptidase A and measuring changes in optical density; and a method of diagnosing acute pancreatitis in a patient by measuring carboxypeptidase A levels in a biological fluid by contacting the fluid with a carboxypeptidase A substrate in the presence and absence of an inhibitor of carboxypeptidase A and measuring changes in optical density.

Brown et al disclose an assay for determining carboxypeptidase A levels and activity in serum by contacting the serum with N-acetyl-phenylalanyl-3-thiaphenylalanine as a substrate. Brown et al also disclose an assay step which measures changes in absorbance after the substrate N-acetyl-phenylalanyl-3-thiaphenylalanine specific for carboxypeptidase A was contacted with a serum sample. In addition, Brown et al disclose that the sensitivity and precision of the assay increased when N-acetyl-phenylalanyl-3-thiaphenylalanine was used as substrate for carboxypeptidase A. Further, the assay was used to detect pancreatitis in patients. See the Abstract and pages 219-225. Thus, Brown et al disclose the method steps claimed except for stating that an inhibitor can be presence.

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However, with respect to using a specific inhibitor of the enzyme carboxypeptidase A, Talley disclose "...the activity of carboxypeptidase A has been found to be strongly inhibited by 2(R)-benzyl succinic acid (Byres et al., "J. Biochem.", Vol.247, p606(1977))." See page 3.

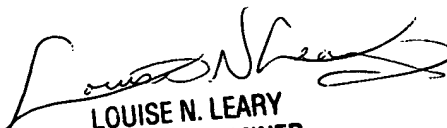
Hence, Brown et al disclose the method steps claimed except for stating that an inhibitor can be presence in a method step for measuring enzymatic activity in a sample which was provided by Talley disclosing the inhibitor 2(R)-benzylsuccinic acid is specific for the enzyme carboxypeptidase A.

It would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the methods claimed for measuring enzyme activity in a sample wherein the enzyme can be carboxypeptidase A comprising the step of measuring enzymatic activity in the presence and absence of a specific inhibitor because Brown et al disclose the method as claimed for measuring the activity and concentration of the enzyme carboxypeptidase A in a serum sample using N-acetyl-phenylalanyl-3-thiaphenylalanine as a substrate specific for carboxypeptidase A to detect pancreatitis except for describing the use of an inhibitor specific for an enzyme or specific for carboxypeptidase A provided by Talley disclosing 2(R)-benzylsuccinic strongly inhibits carboxypeptidase A which is deemed to have previously provided sufficient guidance to practice the method of the invention claimed.

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4. Claims 4-5 are allowable over the prior art of record.

5. Any inquiry concerning this communication should be directed to Louise Leary at telephone number (703) 308-3533.



LOUISE N. LEARY
PRIMARY EXAMINER

May 19, 2000